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REVIEW

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Health related quality of life outcome instruments

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Abstract Health is the most significant part of quality of life. Generally, quality of life outcome instruments used in healthcare confine their attention to health related areas, assessing health related quality of life. The present study aims to describe some commonly used health profile instruments such as the generic measures SF-36, Nottingham Health Profile and Sickness Impact Profile; and the preference-based measures EuroQol and SF-6D. The latter preference-based instruments are increasingly used in outcome studies and obtained data might be used for calculating quality-adjusted life-years.

Keywords Health status · Health status indicators · Quality of life · Quality-adjusted life-years · Questionnaires/standards · Review · SF-36 · Nottingham Health Profile · Sickness Impact Profile · EuroQol · EQ-5D · SF-6D

Introduction

Health is the most significant part of quality of life. Generally, quality of life outcome instruments used in healthcare confine their attention to health related areas, assessing health related quality of life (HRQoL). Commonly assessed areas are (a) physical function, (b) psychological well-being, (c) subjective symptoms, (d) social function and (e) cognitive function. Outcome from HRQoL instruments reflects patient's own experience of gained (or lost) HRQoL and provides a non-disease specific outcome measure. There has been a relative scarcity of such studies in journals dealing with spinal diseases. Three reviews from 2000 describes the literature [17, 45, 79].

The purpose of the present paper is to describe some commonly used health profile instruments [25] such as the generic measures SF-36, Nottingham Health Profile (NHP) and Sickness Impact Profile (SIP); and the preference-based measures EuroQol and SF-6D.

Generic health profile instruments

SF-36

The Medical Outcomes Trust short form questionnaire with 36 questions, most often referred to as SF-36[1], is a measure of general health status relevant across age, disease and treatment groups, widely used and tested in a range of conditions and settings, including spine re-

[1] An SF-36 licence can be obtained at http://www.sf-36.org (accessed 2 October 2005) and a reference kit can be ordered at http://www.qualitymetric.com/products/ProductDetails.aspx?ProductID=468&categoryid=1 (accessed 2 October 2005).

search, e.g. [17, 25, 57, 58, 72, 73]. It is available in a number of languages.[2]

In 1991, the International Quality of Life Assessment launched a project aiming at translating, validating and norming the SF-36 health survey. The SF-36 was published in 1992 by Ware and Sherbourne, and further developed and validated in 1993 and 1994, respectively [47, 48, 74]. It is self- or interviewer-administered and a computerised administration is also available. The form takes about 5–10 min to complete. In general, SF-36 has been shown to be acceptable to people with disabilities [1]. Some changes in wording was suggested for respondents using wheelchairs, for example due to spinal cord injury [49].

The items in SF-36 are divided into eight different domains with overall physical and mental health component summary scores. Domains are physical functioning, role limitations physical, bodily pain, social functioning, general mental health, role limitations emotional, vitality and general health (Table 1). One advantage with SF-36 is the existence of normative data and its documented reliability and validity, e.g. [17].

Since several years, the SF-36 is used for assessments in the Swedish national register for lumbar spine surgery [64, 65]. It has been shown to be useful in describing different diagnostic profiles in persons operated on for lumbar spine disorders [78]. Further it is responsive to changes in outcome in patients operated on and useful in comparing outcome in spine surgery across nations [78]. As described later in the current article, a preference-based score, SF-6D has been developed allowing gained HRQoL to be calculated.

SF-12

SF-12 was developed as an abbreviated version of the SF-36 for use in large surveys of general and specific populations as well as large longitudinal studies of health outcomes.[3] It was developed by Ware et al. and published in 1996 [75] including data on reliability and validity. It can be obtained from the SF Community.[4] Possible administration includes self-, interview-, telephone- or computer-administered recording. SF-12 takes 5 min or less to complete.

Sickness Impact Profile

Sickness Impact Profile[5] was first published in 1976 and a revised version was published by Bergner et al. in 1981 [2]. It is intended for self-administration or interview and contains 136 items. SIP takes 20–30 min to complete and is available in several languages.[6] There are two domains, physical and psychosocial, containing 12 categories (Table 1). The physical domain contains ambulation, mobility, body care and movement. Psychosocial domain contains social interaction, communication, alertness behaviour, emotional behaviour, sleep and rest, eating, home management, recreation and pastimes and employment. Scoring may be done on domain or category levels as well as at the total SIP level.

[2] SF-36 is currently available in Afrikaans, Armenian, Bulgarian, Chinese for Hong Kong, Chinese for Singapore, Chinese for Taiwan, Chinese for the USA, Croatian, Czech, Danish, Dutch, Dutch for Belgium, English for Australia, English for Canada, English for Hong Kong, English for Malaysia, English for New Zealand, English for the Philippines, English for Singapore, English for South Africa, English for Taiwan, English for the UK, Estonian, Finnish, French, French for Belgium, French for Canada, French for Switzerland, German, German for Austria, German for Switzerland, Greek, Gujarati, Hebrew, Hungarian, Icelandic, Iranian, Italian, Italian for Switzerland, Japanese, Japanese for the USA, Kiswahili, Korean, Latvian, Lithuanian, Malay for Malaysia, Malay for Singapore, Malayalam, Marathi, Norwegian, Polish, Portuguese, Portuguese for Brazil, Romanian, Russian, Serbian, Slovak, Slovenian, Spanish, Spanish for Argentina, Spanish for Chile, Spanish for Colombia, Spanish for Costa Rica, Spanish for Guatemala, Spanish for Honduras, Spanish for Mexico, Spanish for Peru, Spanish for Puerto Rico, Spanish for the USA, Spanish for Uruguay, Spanish for Venezuela, Swedish, Tagalog, Telugu, Thai, Turkish, Ukrainian and Vietnamese for the USA. Source: http://www.proqolid.org/, accessed 2 October 2005.

[3] SF-12 is currently available in Afrikaans, Bulgarian, Chinese for Hong Kong, Chinese for Singapore, Chinese for Taiwan, Croatian, Czech, Danish, Dutch, Dutch for Belgium, English for Australia, English for Canada, English for Hong Kong, English for India, English for New Zealand, English for South Africa, English for Taiwan, English for the UK, Estonian, Finnish, French, French for Belgium, French for Canada, French for Switzerland, German, German for Austria, German for Switzerland, Greek, Gujarati, Hebrew, Hindi, Hungarian, Italian, Italian for Switzerland, Japanese, Kannada, Korean, Latvian, Lithuanian, Malay for Malaysia, Malay for Singapore, Malayalam, Marathi, Norwegian, Polish, Portuguese, Portuguese for Brazil, Romanian, Russian, Slovak, Slovenian, Spanish, Spanish for Argentina, Spanish for Chile, Spanish for Mexico, Spanish for Puerto Rico, Spanish for the USA, Swedish, Tagalog, Telugu, Thai, Turkish, Ukrainian, Xhosa and Zulu. Source: http://www.proqolid.org/, accessed 2 October 2005.

[4] http://www.sf-36.org/tools/sf12.shtml, accessed 2 October 2005.

[5] The instrument can be ordered from Medical Outcomes Trust, a not for profit organisation, at http://www.outcomes-trust.org/instruments/SIPpack.htm (accessed 25 September 2005). The package includes a copy of the instrument including royalty-free permission to use and reproduce and user manual.

[6] Sickness Impact Profile is currently available in Arabic, Chinese for Hong-Kong, Danish, Dutch, Dutch for Belgium, English for Mexico, English for the UK, Finnish, French, French for Belgium, German, Italian, Norwegian, Portuguese, Russian, Spanish, Spanish for Mexico, Spanish for the USA (Chicano Spanish for the Southwest USA), Swedish, Tamil and Thai. Source: http://www.proqolid.org/, accessed 2 October 2005.

Table 1 Domains and/or categories for three generic health profile instruments

SF-36	Nottingham Health Profile	Sickness impact profile
Physical functioning	Physical mobility	*Physical*
Role limitations due to physical problems	Pain	Ambulation
Bodily pain	Social isolation	Mobility
General health perceptions	Emotional reactions	Body care
Vitality	Energy	Movement
Social functioning	Sleep	*Psychosocial*
Role limitations due to emotional problems		Social interaction
Mental health		Communication
Health transition		Alertness behaviour
		Emotional behaviour
		Independent
		Sleep and rest
		Eating
		Home management
		Recreation
		Employment

The SIP is a reliable and valid instrument [17, 45], it has been used in several spine studies such as cervical disc hernia and neck pain [32, 44, 52, 54], lumbar disc herniation, spinal stenosis and back pain [41, 43, 56, 66], vertebral deformities and osteoporosis [24, 53], chronic pain and spinal cord stimulation [9, 51, 63, 77], ankylosing spondylitis [33, 34] and in evaluation of iliac crest donor problems [29].

Nottingham Health Profile

Nottingham Health Profile[7] was developed by Hunt et al. and published in 1981 [35]. It is intended for self-administration and contains 38 items in six sections and takes about 10 min to complete, it is available in different languages[8] and can be self- or interviewer-administrated. Sections or categories are physical mobility, pain, social isolation, emotional reactions, energy and sleep (Table 1). Each item is weighted and dimensions scores range from 0 to 100. Mean score is calculated across all items. The NHP was designed to reflect a lay perception of health status as opposed to the professional perception.

Use of the NHP in musculo-skeletal research includes for example studies on osteoporosis [18, 23, 68], vertebroplasty [19, 42], sciatica [40], low back fusions [60] and other musculo-skeletal disorders [15].

Preference-based health profile instruments

Preference-based HRQoL instruments are increasingly used in outcome studies. The recorded values or ratings are obtained from patients themselves. Values or indexes are commonly between 0 (death) and 1 (full health). There are different techniques to obtain indexes based on a group's estimate of differences in perceived health status. Time Trade-off is used in EuroQol [20, 21]. Values for SF-6D have been obtained with both Standard Gamble and Visual Analogue Scale (VAS) [4, 5]. Tosteson published an excellent review in 2000 [69].

Data from preference-based HRQoL outcome instruments are used for calculating QALYs (quality-adjusted life-years), which is needed in the analysis of monetary aspects of different interventions, e.g. [31]. The denominator in cost–benefit analysis is usually a monetary unit, for example Euros—the effect or consequence of an intervention is expressed in cost for intervention per Euro benefit. There might be reservations to value benefits in monetary units; some would instead prefer to use a preference-based utility measure such as gained HRQoL. If increased HRQoL is assessed and multiplied with the length of time affected, one can express this generic outcome in gained QALYs (Fig. 1). For example, a 64-year-old female patient is operated on for a lumbar spinal stenosis. Her HRQoL increases from 0.45 preoperatively to 0.8 postoperatively (K. A. Jansson et al., submitted for publication), a gain of 0.35. The expected survival time is 10 years. Thus the gain in QALY is $0.35 \times 10 = 3.5$ QALYs. The calculated cost per gained QALY is often used in cost–utility analysis.

[7] Address for contact: Dr. Stephen McKenna, Director of Research, Galen Research, Enterprise House, Manchester Science Park, Lloyd Street North, Manchester M15 6SE, UK. Tel.: +44-161-2264446; Fax: +44-161-2264478; E-mail: smckenna@galen-research.com. Source: http://www.blackwell-synergy.com/doi/full/10.1111/j.1524-4733.2004.7s110.x, accessed 4 October 2005.

[8] Nottingham Health Profile is currently available in Arabic, Danish, Dutch, English for the USA, Finnish, French, German, Greek, Hungarian, Italian, Japanese, Norwegian, Portuguese for Brazil, Spanish and Swedish. Source: http://www.proqolid.org/, accessed 2 October 2005.

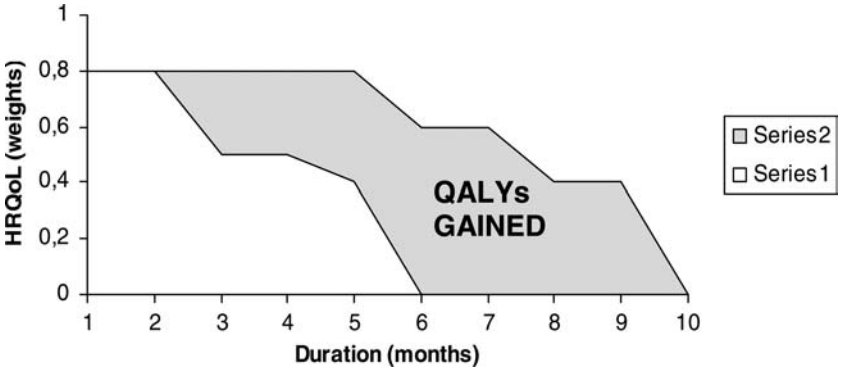

Fig. 1 Drawing illustrating quality-adjusted life-years gained. *1* on the vertical scales denotes perfect health and *0* dead

EuroQol (EQ-5D)

EuroQol was concurrently developed in five languages (Dutch, Finnish, Norwegian, Swedish and UK English) by an interdisciplinary team of European researchers (the EuroQol Group) and published in 1990 [67]. The instrument is called EQ-5D and can be obtained at the EuroQol Group homepage.[9] There are official translations in many languages[10] and 16 more are awaiting official status.

EQ-5D is designed for self-administration (guidelines for observer, telephone and proxy use are available) and simplicity was an important component of the design. It is intended for use in population health surveys or in combination with a condition-specific instrument for assessment to a specific condition (e.g. a spine disorder). It has good reliability and validity [3, 7, 22, 36, 37, 39, 55] and contains five dimensions (mobility, self-care, usual activity, pain/discomfort and anxiety/depression) rated on three levels (''no problem,'' ''some problem'' or ''extreme problem''). Preferences were assessed using Time Trade-off values from a subset of health states from a UK population [21]. The score ranges from 0 (death) to 1 (perfect health). In the modelling of the algorithm for the population-based tariff a factor (interaction term called N3) of −0.269 was included if level 3 (''extreme problems'') occurred within at least one dimension [21]. This results in negative scores for some health states. The EQ-5D algorithm tends to cluster scores in the upper extreme close to 1.0 and around 0.45 [6]. This was also noted in two recent clinical studies (K. A. Jansson et al., submitted for publication) [38] of lumbar disk and stenosis surgery. The second part of EQ-5D is a 20 cm VAS with end points labelled ''Worst imaginable health state'' and ''Best imaginable health state.''

Three types of data can be displayed [8] from EQ-5D: (a) a descriptive profile, indicating the extent of problems on each of the five dimensions, (b) a population-weighted health score, based on the descriptive data and (c) a self-rated assessment of perceived health status based on the VAS.

EuroQol is increasingly used in spine research, e.g. [16, 27, 28, 46, 59, 61, 62, 76], and also as outcome instrument in National Quality Registers of spine surgery, e.g. [38, 64, 65].

SF-6D

The SF-6D is a preference-based scoring system utilising six dimensions from SF-36, thus permitting calculations of utilities from SF-36 responses. It was developed in UK by Brazier et al. [4, 5] and may be obtained from the university.[11]

[9] http://www.euroqol.org, accessed 2 October 2005.

[10] EQ-5D is currently available in Afrikaans (for South Africa), Bulgarian, Catalan, Chinese (for China, Hong Kong, Singapore, Taiwan), Croatian, Czech, Danish, Dutch (for Belgium, the Netherlands), English (for Australia, Canada, New Zealand, UK (includes Ireland), Singapore, South Africa, USA), Estonian, Finnish, French (for Belgium, France, Canada, Switzerland), German (for Germany, Austria, Switzerland), Greek, Hebrew, Hungarian, Indonesian, Italian, Japanese, Latvian, Lithuanian, Malay (for Malaysia), Norwegian, Polish, Portuguese (for Brazil, Portugal), Romanian, Russian (for Israel, Russia), Slovakian, Spanish (for Argentina, Chile, Colombia, Costa Rica, Guatemala, Mexico, Peru, Spain, Uruguay, USA, Venezuela), Slovenian, Swedish, Thai and Turkish. Source: http://www.euroqol.org/web/users/language_a.php/, accessed 2 October 2005.

[11] http://www.shef.ac.uk/scharr/sections/heds/projects/sf-6d.html (accessed 14 October 2005). The SF-6D is copyrighted and is available on a license basis. A license is available free of charge for all non-commercial applications including work funded by research councils, Government agencies and charities. For commercial applications there will be a per study license (e.g. clinical trial), though an open license for a fixed period is available. The SF-6D is being used in software available from Quality Metric (www.qualitymetric.com).

The eight dimensions from SF-36 were reduced to six by omitting general health perceptions and combining role limitations due to physical and emotional problems. The six dimensions included are physical functioning, role limitations, social functioning, pain, mental health and vitality, each dimension containing up to six levels generating 18,000 (6×4×5×6×5×5) unique health states. A model identified 249 health states out of the 18,000 [5].

The SF-6D preference weights were obtained from a sample of the general population using the standard gamble method [5]. Samples of the general population were asked to value the selection of health states (249), in which the model had estimated to predict all the 18,000 health states described. The SF-6D algorithm generates health state values from 1.0 (no problems of any of the six dimensions) to 0.296 (most impaired level on all six dimensions). There are floor effects reported [5, 6] indicating that SF-6D over predict poorer health states compared to EQ-5D. Good reliability and validity have been reported [6, 55].

Some comparisons between EQ-5D and SF-6D

Several studies compare preference-based instruments [6, 17, 39, 46, 50, 55, 69]. On average, the SF-6D generates scores that exceed EQ-5D. The difference (although statistically significant) is very small, only 0.045. However, the two instruments generate different scores over the range of ill health, indicated by the difference in median score level where EQ-5D scores exceed the SF-6D values. There are ceiling effects for EQ-5D, floor effects for SF-6D and clustering effects for EQ-5D. An advantage for SF-6D is the possibility to derive the outcome in health utility from the SF-36. An advantage for EQ-5D is the huge reference data available containing health scores from normal populations, as well as different diseases, e.g. [10–14].

Minimal important difference (MID) for EQ-5D and SF-6D was reported by Walters and Frazier [70, 71]. This is an important measure for power calculations in studies. In the latter study [71], eight longitudinal investigations in 11 different patient groups that used both instruments were reviewed. The MID for EQ-5D was 0.074 and for SF-6D 0.041. The difference is probably due to the approximately double range of the EQ-5D scale.

Influence from co-morbidity

Co-morbidity is a factor, significantly influencing outcome in most aspects [26]. One well-known way of classifying the effect from existing co-morbidity is the American Association of Anaesthetists (ASA) score.[12] The ASA score subjectively categorises patients into five subgroups by preoperative physical fitness. Since underlying fitness is an important predictor of survival from surgery, the ASA score has some correlation with outcome. As it is simple and widely understood, it is commonly used as a part of the preoperative assessment, and is an easy tool for audit.

Another score, diagnose-based rather than symptom-based, was recently published [30], called the Functional Co-morbidity Index. It is based on 18 diagnoses and showed strong correlation with the SF-36 physical function subscale. The index correctly classified patients into high and low function in 77% of the cases. There is need for future studies addressing the effect of co-morbidity on HRQoL outcome.

Conclusion

There are several robust HRQoL instruments for use in spinal research. With the increased focus on healthcare resources, it is recommended that a preference-based HRQoL measure is included in the outcome so that gained QALYs can be calculated. It would be advantageous if the effect of co-morbidity on HRQoL outcome is addressed in future studies.

[12] http://www.asahq.org/clinical/physicalstatus.htm, accessed 12 October 2005.

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